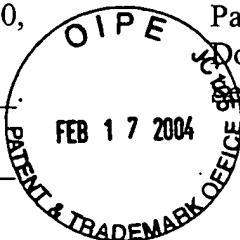


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on February 10, 2004

Glenn P. Ladwig
Glenn P. Ladwig, Patent Attorney



INFORMATION DISCLOSURE
STATEMENT
Examining Group 1632
Patent Application
Docket No. USF-182XC1
Serial No. 10/655,873

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1632
Applicants : Shyam S. Mohapatra, Mukesh Kumar
Serial No. : 10/655,873
Filed : September 5, 2003
For : Genetic Adjuvants for Immunotherapy

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

The applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Glenn P. Ladwig

Glenn P. Ladwig

Patent Attorney

Registration No. 46,853

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

GPL/mv

Attachments: Form PTO/SB/08 (5 pages); copies of references cited therein.



PTO/SB/08A (08-03)

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<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete if Known	
				Application Number	10/655,873
				Filing Date	September 5, 2003
				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
Examiner Name					
Sheet	1	of	5	Attorney Docket Number	USF-182XC1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-6,489,306 B2	12-03-2002	Mohapatra et al.	All
	U2	US-2003/0198624 A1	10-23-2003	Mohapatra et al.	All
	U3	US-2001/0006951 A1	07-05-2001	Mohapatra et al.	All
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY		
	F1	WO 03/074561 A1	09-12-2003	Univ. South Florida	All
	F2				
	F3				
	F4				
	F5				
	F6				
	F7				

Examiner Signature	Date Considered
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Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

5

Complete if Known

Application Number	10/655,873
Filing Date	September 5, 2003
First Named Inventor	Shyam S. Mohapatra
Group Art Unit	1632
Examiner Name	

Attorney Docket Number **USF-182XC1**

NON PATENT LITERATURE DOCUMENTS

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	R1	BARNES, P.J. "Cytokine-directed therapies for asthma" <i>J. Allergy Clin. Immunol.</i> , 2001, 108:S72-76.	
	R2	BEHERA, A.K. et al. "Adenovirus-mediated interferon γ gene therapy for allergic asthma: involvement of interleukin 12 and STAT4 signaling" <i>Human Gene Therapy</i> , 2002, 13:1697-1709.	
	R3	BORASCHI, D. et al. "Interferons inhibit LTC ₄ production in murine macrophages" <i>J. Immunol.</i> , 1987, 138:4341-4346.	
	R4	BYRNES, A.A. et al. "Type I interferons and IL-12: convergence and cross-regulation among mediators of cellular immunity" <i>Eur. J. Immunol.</i> , 2001, 31:2026-2034.	
	R5	CHEN, Q. et al. "Development of Th-1-type immune responses requires the type I cytokine receptor TCCR" <i>Nature</i> , 2000, 407:916-920.	
	R6	COHEN, J. "IL-12 deaths: explanation and a puzzle" <i>Science</i> , 1995, 270:908.	
	R7	DAINES, M.O. and HERSHY, G. "A novel mechanism by which interferon- γ can regulate interleukin (IL-13) responses" <i>J. Biol. Chem.</i> , 2002, 277(12):10387-10393.	
	R8	DENG, J.C. et al. "Transient transgenic expression of gamma interferon promotes <i>Legionella pneumophila</i> clearance in immunocompetent hosts" <i>Infection and Immunity</i> , 2001, 69(10):6382-6390.	
	R9	FORD, J.G. et al. "IL-13 and IFN- γ : interactions in lung inflammation" <i>J. Immunol.</i> , 2001, 167:1769-1777.	
	R10	GAVETT, S.H. et al. "Interleukin 12 inhibits antigen-induced airway hyperresponsiveness, inflammation, and Th2 cytokine expression in mice" <i>J. Exp. Med.</i> , 1995, 182:1527-1536.	
	R11	GURUJEYALAKSHMI, G. and GIRI, S.N. "Molecular mechanisms of antifibrotic effect of interferon gamma in bleomycin-mouse model of lung fibrosis: downregulation of TGF- β and procollagen I and III gene expression" <i>Exp. Lung Res.</i> , 1995, 21:791-808.	
	R12	HANSEN, G. et al. "Allergen-specific Th1 cells fail to counterbalance Th2 cell-induced airway hyperreactivity but cause severe airway inflammation" <i>J. Clin. Invest.</i> , 1999, 103:175-183.	
	R13	HANSEN, G. et al. "CD4 $^{+}$ T helper cells engineered to produce latent TGF- β 1 reverse allergen-induced airway hyperreactivity and inflammation" <i>J. Clin. Invest.</i> , 2000, 105:61-70.	

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<p>Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)</p>				Complete if Known	
Sheet	3	of	5	Application Number	10/655,873
				Filing Date	September 5, 2003
				First Named Inventor	Shyam S. Mohapatra
				Group Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-182XC1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	R14	HASBOLD, J. et al. "Integrating signals from IFN- γ and IL-4 by B cells: positive and negative effects on CD40 ligand-induced proliferation, survival, and division-linked isotype switching to IgG1, IgE, and IgG2a" <i>J. Immunol.</i> , 1999, 163:4175-4181.		
	R15	HASKO, G. and SZABO, C. "IL-12 as a therapeutic target for pharmacological modulation in immune-mediated and inflammatory diseases: regulation of T helper 1/T helper 2 responses" <i>Brit. J. Pharm.</i> , 1999, 127:1295-1304.		
	R16	HE, T-C. et al. "A simplified system for generating recombinant adenoviruses" <i>Proc. Natl. Acad. Sci. USA</i> , 1998, 95:2509-2514.		
	R17	KAPLAN, M.H. et al. "Impaired IL-12 responses and enhanced development of Th2 cells in Stat4-deficient mice" <i>Nature</i> , 1996, 382:174-177.		
	R18	KAPLAN, M.H. et al. "A signal transducer and activator of transcription (Stat)4-independent pathway for the development of T helper type 1 cells" <i>J. Exp. Med.</i> , 1998, 188(6):1191-1196.		
	R19	KIRKWOOD, J.M. et al. "Interferon alfa-2b adjuvant therapy of high-risk resected cutaneous melanoma: The Eastern Cooperative Oncology Group trial EST 1684" <i>J. Clin. Oncology</i> , 1996, 14(1):7-17.		
	R20	KITAGAWA, M. et al. "Interferon- γ enhances interleukin 12 production in rheumatoid synovial cells via CD40-CD154 dependent and independent pathways" <i>J. Rheumatology</i> , 2001, 28:1764-1771.		
	R21	KUMAR, M. et al. "Intranasal IFN- γ gene transfer protects BALB/c mice against respiratory syncytial virus infection" <i>Vaccine</i> , 2000, 18:558-567.		
	R22	KUMAR, M. et al. "IFN- γ and IL-12 plasmid DNAs as vaccine adjuvant in a murine model of grass allergy" <i>J. Allergy Clin. Immunol.</i> , 2001, 108:402-408.		
	R23	LACK, G. et al. "Nebulized but not parenteral IFN- γ decreases IgE production and normalizes airways function in a murine model of allergen sensitization" <i>J. Immunol.</i> , 1994, 152:2546-2554.		
	R24	LI, X-M. et al. "Mucosal IFN- γ gene transfer inhibits pulmonary allergic responses in mice" <i>J. Immunol.</i> , 1996, 157:3216-3219.		
	R25	LIGHVANI, A.A. et al. "T-bet is rapidly induced by interferon- γ in lymphoid and myeloid cells" <i>PNAS</i> , 2001, 98(26):15137-15142.		
	R26	MATSUSE, H. et al. "Recurrent respiratory syncytial virus infections in allergen-sensitized mice lead to persistent airway inflammation and hyperresponsiveness" <i>J. Immunol.</i> , 2000, 164:6583-6592.		

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Sheet	4	of	5	Application Number	10/655,873
				Filing Date	September 5, 2003
				First Named Inventor	Shyam S. Mohapatra
				Group Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-182XC1

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	R27	MINSHALL, E.M. et al. "Eosinophil-associated TGF- β , mRNA expression and airways fibrosis in bronchial asthma" <i>Am. J. Respir. Cell Mol. Biol.</i> , 1997, 17:326-333.			T ²
	R28	MORRISON, D.F. and MURTAUGH, M.P. "Adenovirus-mediated expression of interleukin-1 receptor antagonist in swine cells in vitro and in vivo" <i>Veterinary Immunol. and Immunopatholgy</i> , 2001, 78:71-81.			
	R29	MOSMANN, T.R. and COFFMAN, R.L. "TH1 and TH2 cells: different patterns of lymphokine secretion lead to different functional properties" <i>Ann. Rev. Immunol.</i> , 1989, 7:145-173.			
	R30	MULLEN, A.C. et al. "Role of T-bet in commitment of T _H 1 cells before IL-12-dependent selection" <i>Science</i> , 2001, 292:1907-1909.			
	R31	O'GARRA, A. and ARAI, N. "The molecular basis of T helper 1 and T helper 2 cell differentiation" <i>Cell Biol.</i> , 2000, 10:542-550.			
	R32	OPPMANN, B. et al. "Novel p19 protein engages IL-12p40 to form a cytokine, IL-23, with biological activities similar as well as distinct from IL-12" <i>Immunity</i> , 2000, 13:715-725.			
	R33	PIERKES, M. et al. "Decreases release of histamine and sulfidoleukotrienes by human peripheral blood leukocytes after wasp venom immunotherapy is partially due to induction of IL-10 and IFN- γ production of T cells" <i>J. Allergy Clin. Immunol.</i> , 1999, 103:326-332.			
	R34	RANDOLPH, D.A. et al. "Modulation of airway inflammation by passive transfer of allergen-specific Th1 and Th2 cells in a mouse model of asthma" <i>J. Immunol.</i> , 1999, 162:2375-2383.			
	R35	ROBINSON, D.S. et al. "Predominant T _H 2-like bronchoalveolar T-lymphocyte population in atopic asthma" <i>N. Engl. J. Med.</i> , 1992, 326:298-304.			
	R36	RUDICK, R.A. et al. "Management of multiple sclerosis" <i>J. Engl. J. Med.</i> , 1997, 337(22):1604-1611.			
	R37	SCHWARZE, J. et al. "Local treatment with IL-12 is an effective inhibitor of airway hyperresponsiveness and lung eosinophilia after airway challenge in sensitized mice" <i>J. Allergy Clin. Immunol.</i> , 1998, 102:86-93.			
	R38	STAMPFLI, M.R. et al. "GM-CSF transgene expression in the airway allows aerosolized ovalbumin to induce allergic sensitization in mice" <i>J. Clin. Invest.</i> , 1998, 102:1704-1714.			
	R39	STIRLING, R.G. and CHUNG, K.F. "New immunological approaches and cytokine targets in asthma and allergy" <i>Eur. Respir. J.</i> , 2000, 16:1158-1174.			

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				Filing Date	September 5, 2003
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	R40	SUR, S. et al. "Mucosal IL-12 inhibits airway reactivity to methacholine and respiratory failure in murine asthma" <i>Exp. Lung Res.</i> , 2000, 26:477-489.			
	R41	TANG, C. et al. "Th type 1-stimulating activity of lung macrophages inhibits Th2-mediated allergic airway inflammation by an IFN- γ -dependent mechanism" <i>J. Immunol.</i> , 2001, 166:1471-1481.			
	R42	THIERFELDER, W.E. et al. "Requirement for Stat4 in interleukin-12-mediated responses of natural killer and T cells" <i>Nature</i> , 1996, 382:171-174.			
	R43	THIVIERGE, M. et al. "IL-13 and IL-4 up-regulated cysteinyl leukotriene 1 receptor expression in human monocytes and macrophages" <i>J. Immunol.</i> , 2001, 167:2855-2860.			
	R44	TRINCHIERI, G. "Interleukin-12: a cytokine produced by antigen-presenting cells with immunoregulatory functions in the generation of T-helper cells type 1 and cytotoxic lymphocytes" <i>Blood</i> , 1994, 84(12):4008-4027.			
	R45	UMETSU, D.T. and DEKRUYFF, R.H. "T _{H1} and T _{H2} CD4 $^{+}$ cells in human allergic diseases" <i>J. Allergy Clin. Immunol.</i> , 1997, 100(1):1-6.			
	R46	WALTER, D.M. et al. "IL-18 gene transfer by adenovirus prevents the development of and reverses established allergen-induced airway hyperreactivity" <i>J. Immunol.</i> , 2001, 166:6392-6398.			
	R47	WANG, I-M. et al. "An IFN- γ -inducible transcription factor, IFN consensus sequence binding protein (ICSBP), stimulates IL-12 p40 expression in macrophages" <i>J. Immunol.</i> , 2000, 165:271-279.			
	R48	ZABNER, J. et al. "Repeat administration of an adenovirus vector encoding cystic fibrosis transmembrane conductance regulator to the nasal epithelium of patients with cystic fibrosis" <i>J. Clin. Invest.</i> , 1996, 97:1504-1511.			
	R49				
	R50				
	R51				
	R52				

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